K003880

5 510(k) Summary

MAY 1 6 2001

This summary of the 510(k) premarket notification for the Concentric HD Guide Catheter is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

5.1 Manufacturer

Concentric Medical Inc.
2585 Leghorn Street
Mountain View, CA. 94043
Telephone: (650) 938-2100
Registration #: Pending assignment by FDA

5.2 Contact Person

Linda Bradley
Senior Regulatory Affairs Specialist

5.3 Date Prepared

December 15, 2000

5.4 Classification

Percutaneous Catheter, 21CFR 870.1250 – Class II

5.5 Trade Name

Concentric HD Guide Catheter™

5.6 Generic/Common Name

Percutaneous Catheter

5.7 Predicate Device

Cordis Envoy® MAX ID Guiding Catheter (K962362)

5.8 Action taken to comply with Section 514 of the Act

No applicable mandatory performance standards or special controls exist for this device.

5.9 Intended Use

The Concentric HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate micro catheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

5.10 Product Description

The Concentric HD Guide Catheter is a single lumen, variable stiffness catheter that consists of a braided shaft with an outer liner and an inner liner. The shaft has a radiopaque distal end.

5.11 Substantial Equivalence

The Concentric HD Guide Catheter is intended for use in interventional radiological procedures. It is substantially equivalent to other devices currently on the market for use in interventional radiological procedures. The Concentric HD Guide Catheter is equivalent to the Cordis Envoy MAX ID Guiding Catheter (K962362). The Concentric HD Guide Catheter is substantially equivalent to the predicate device with regards to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Concentric HD Guide Catheter and the predicate device do not raise any new issues of safety or effectiveness.

5.12 Testing in Support of Substantial Equivalence

Performance, biocompatibility and microbiological testing will be conducted and the results of the testing will verify that the Concentric HD Guide Catheter performs as designed and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2001

Mr. Kevin F. MacDonald
Concentric Medical, Inc.
2585 Leghorn Street
Mountain View, CA 94043

Re: K003880
Concentric HD Guide Catheter™
Regulation Number: 870.1250
Regulatory Class: II (two)
Product Code: DQY
Dated: March 16, 2001
Received: March 19, 2001

Dear Mr. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K003880

Device Name: Concentric HD Guide Catheter™

Indications for Use:

The Concentric HD Guide Catheter™ is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate micro catheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use __
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003880